

REMARKS

Claims 36-39 are currently amended. Claim 40 is new. No new matter is added. Reconsideration of the pending application is requested.

I: The Rejection of Claims 36-39 under 35 U.S.C. 112 (Written Description)

Claims 36-39 were rejected for allegedly containing new matter. Specifically, the Examiner states that the limitations "at least 51%, 52%, 54% or 56% are not supported in the specification. Applicant traverses this requirement.

Initially, Applicant has amended claims 36-39 to remove the terms "at least".

Notwithstanding any amendment, Applicant notes the following. A disclosure does not have to provide *in haec verba* support in order to satisfy the written description requirement), the prior application must indicate to a person skilled in the art that the inventor was "in possession" of the invention as later claimed. *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985). To satisfy the written description requirement, "the missing descriptive matter must necessarily be present in the [original] application's specification such that one skilled in the art would recognize such a disclosure." *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159 (Fed. Cir. 1998); see also *Martin v. Mayer*, 823 F.2d 500, 505 (Fed. Cir. 1987) (holding that the written description requirement is "not a question of whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure. . . . Rather, it is a question whether the application necessarily discloses that particular device") (emphasis in original). This requires that the written description actually or inherently disclose the claim element. See *Turbo Care Div. of Demag Delaval Turbomachinery Corp. v. Gen. Elec. Co.*, 264 F.3d 1111, 1118-20 (Fed. Cir. 2001).

The specification provides on page 5:

To obtain the best protection of the detergent enzyme it is important that the granule core, and optionally the coating comprise enough buffer capacity to withstand the hostile alkaline components in the environment. It is found that the granule core must comprise at least 10 % w/w of acidic buffer component, in particular more than 25 % w/w of acidic buffer component, in particular more than 40 % w/w of acidic buffer component, in particular more than 50 % w/w of acidic buffer component, in particular more than 60 % w/w of acidic buffer component, in particular more than 70 % w/w of acidic buffer component, in particular more than 80 % w/w of acidic buffer component. If the coating includes an acidic buffer component it should particularly constitute more than 40 % w/w of the coating, more particularly more than 50 % w/w of the coating.

One of skill in the art would clearly understand that the term "more than" broadens the numbers provided in the specification. Further, since Applicant included multiple designations e.g., more than 50%, more than 60%, more than 70%, it is clear that Applicant was in possession of the percentages between the numbers, including at least 51%, 52%, 54% or 56%. Clearly these percentages are inherently in the description above and in the possession of the Applicant at the time of filing. Reconsideration is urged.

II The Rejection of Claims 18-24, 26-27, 29-39 under 35 U.S.C. 103(a)

Claims 18-24, 26-27, 29-39 stand rejected as obvious in light of U.S. Patent No. 4,009,076 (hereinafter referred to simply as "Green"). Applicant traverses this rejection.

"Section 103 forbids issuance of a patent when 'the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.'" *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 298, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, (3) the level of skill in the art, and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

The Supreme Court stated that "[o]ften, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418. The Court also noted that "[t]o facilitate review, this analysis should be made explicit." *Id.* at 418. (Citing *In re Kahn*, 441 F.3d 977, 988 (Fed Cir. 2006) ("[R]jections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness")). However, "the analysis need not seek out precise teachings directed to a specific subject matter of the challenged claim, for a court can take into account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.*

In rejecting claims under 35 U.S.C. § 103(a), the examiner bears the initial burden of establishing a *prima facie* case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992); see also *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984). Only if this initial burden

is met does the burden of coming forward with evidence or argument shift to the appellant. See *Oetiker*, 977 F.2d at 1445; see also *Plasecki*, 745 F.2d at 1472. Obviousness is then determined on the basis of the evidence as a whole and the relative persuasiveness of the arguments. *Id.*

The Examiner has failed to make a *prima facie* case of obviousness, and the rejection is in error.

The present disclosure relates to granules including detergent enzymes and acidic buffer components in the core. The acidic buffer components serve the purpose of stabilizing the detergent enzyme containing granules by neutralizing hostile alkaline materials in the environment. Accordingly, the present disclosure provides stabilized solid formulations of detergent enzymes, particularly formulations showing improved stability of the enzyme in hostile alkaline powder detergents. The present disclosure explains that the Applicant has surprisingly found that the stability problem in granules can be solved by controlling the pH in the environment closest to and surrounding the detergent enzyme having an alkaline pH activity optimum by adding acidic buffer components to the granules. Indeed it was surprising that detergent enzymes having an alkaline pH activity optimum could be stabilized by acidic compounds. Normally one would expect that an enzyme which functions optimally at alkaline pH would prefer and be more stable in an alkaline environment of for example alkaline buffer salts.

Green relates to enzyme granules prepared having a granule core of solid material carrying an enzyme and a solid coating of plasticized resin free of the enzyme. The plasticized resin can be dextrin or sodium lignosulphonate containing a plasticizer such as glucose, sucrose urea, glycerol or ethylene glycol. The granules are made by spraying the enzyme-containing core with a concentrated aqueous solution of the plasticized resin.

The Examiner has correctly explained that Green is deficient in that Green fails to specifically disclose the carrier to be sodium hexametaphosphate in the amount claimed, and the pH and Pk_a values of the acid buffer component. This is true because it was not known that the claimed conditions would be effective for improving storage stability of granules including detergent enzyme having an alkaline pH activity optimum.

The Examiner, without any scientific evidence or appropriate rationale has concluded it would have been obvious to have selected sodium hexametaphosphate as the carrier because this is one of the suitable carriers taught by Green to optimize its proportions within the amounts disclosed for sodium tripolyphosphates as they are used as carrier equivalents because it has been held to be obvious to select a value in a known range by optimization for the best results. Rejections on obviousness grounds cannot be sustained by mere conclusory statements;

instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. Here there is no detailed rationale given by the Examiner other than the assumption that one of skill in the art would have applied Green constituents and amounts in order to optimize the presently claimed granule.

It is speculative that the Green constituents would have been excellent at improving the storage stability of the granule. One of ordinary skill in the art would not envision the success of using the acidic buffer component over the alkaline constituents. Further, there is no disclosure that the acidic buffer component having a pH of 1 to below 7 when measured as a 10 % aqueous solution and a pK_a in the range of 4 to 9 would increase the storage stability. Thus, Applicant believes there is no evidence given by Green that the acidic buffer components are suitable for increasing stability. A skilled person in the art would have no reasonable expectation of success that acidic buffer components are suitable for increasing stability. Applicant directs the Examiner's attention to Applicant's examples and results therein. Example 1 shows the addition of buffer salt increases stability. Example 2 shows the acidic buffer component improved stability, while the alkaline buffer decreased stability compared to inert salt. Example 3 shows an increase in buffer capacity by using both in the core and in the coating increases storage stability. Finally, Example 5 shows polyacrylic acid buffer coating increasing storage stability. Applicant has clearly contributed to the art and surprisingly shown unexpected advantages in using the acidic buffer component in combination with a detergent enzyme having an alkaline pH activity optimum.

Greene does not provide the requisite teaching, suggestion and motivation to use the acidic buffer component in accordance with Claim 18. Certainly there is no scientific evidence or sound scientific reasoning offered by the Office to do so other than a baseless claim relating to routine optimization. The Office has improperly undermined the requirement for a reasonable expectation of success. More specifically, the conclusive statements offered by the Office are devoid of scientific reasoning.

Applicant further notes that Green is devoid of any suggestion to apply the acidic buffer component for the purpose of promoting stability as advanced by the Examiner, except from using Applicants' disclosure as a template through hindsight reconstruction of Applicants' claim. Thus, the Examiner has erroneously retraced the path of the inventor with hindsight --discounting the number of complexities of the alternatives in order to conclude that the specifically claimed stabilized granules were obvious. This reasoning is always inappropriate for an obviousness test based on the language of Title 35 that requires the analysis to examine "the subject matter as a

whole" to ascertain if it "would have been obvious at the time the invention was made." 35 U.S.C. § 103(a).

Applying a non-rigid TSM analysis, one of ordinary skill in the art would not be motivated by Green to make a granule that combines a detergent enzyme having an alkaline pH activity optimum and an acidic buffer component having a pH of 1 to below 7 when measured as a 10 % aqueous solution and a pK_a in the range of 4 to 9, wherein more than 50% w/w of the core is acidic buffer component. There is certainly no suggestion to do so.

For the foregoing reasons, Applicant submits that the claims overcome this rejection under 35 U.S.C. § 103(a). Applicants respectfully request reconsideration and withdrawal of the rejection.

III. The Rejection of Claim 28 under 35 U.S.C. 103(a)

Claim 28 stands rejected as obvious over Green in light of U.S. Patent No. 6,355,697 (hereinafter referred to simply as "Rahman").

Claim 28 depends upon Claim 18, thus is not obvious for the same reasons Claim 18 is not obvious.

IV. The Rejection of Claims 18-24, 26, 29-39 under 35 U.S.C. 103(a).

Claims 18-24, 26, 29-39 stand rejected as obvious in light of U.S. Patent No. 5,858,952 (hereinafter referred to simply as "Izawa") in view of U.S. Patent No. 6,242,407 (hereinafter referred to simply as "Bertacchi"). Applicants traverse this rejection.

"Section 103 forbids issuance of a patent when 'the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.'" *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 298, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, (3) the level of skill in the art, and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

The Supreme Court stated that "[o]ften, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR*,

550 U.S. at 418. The Court also noted that "[t]o facilitate review, this analysis should be made explicit." *Id.* at 418. (Citing *In re Kahn*, 441 F.3d 977, 988 (Fed Cir. 2006) ("[R]jections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness")). However, "the analysis need not seek out precise teachings directed to a specific subject matter of the challenged claim, for a court can take into account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.*

In rejecting claims under 35 U.S.C. § 103(a), the examiner bears the initial burden of establishing a *prima facie* case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992); see also *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984). Only if this initial burden is met does the burden of coming forward with evidence or argument shift to the appellant. See *Oetiker*, 977 F.2d at 1445; see also *Piasecki*, 745 F.2d at 1472. Obviousness is then determined on the basis of the evidence as a whole and the relative persuasiveness of the arguments. *Id.*

The Examiner has failed to make a *prima facie* case of obviousness, and the rejection is in error.

The present disclosure relates to granules including detergent enzymes and acidic buffer components in the core. The acidic buffer components serve the purpose of stabilizing the detergent enzyme containing granules by neutralizing hostile alkaline materials in the environment. Accordingly, the present disclosure provides stabilized solid formulations of detergent enzymes, particularly formulations showing improved stability of the enzyme in hostile alkaline powder detergents. The present disclosure explains that the Applicant has surprisingly found that the stability problem in granules can be solved by controlling the pH in the environment closest to and surrounding the detergent enzyme having an alkaline pH activity optimum by adding acidic buffer components to the granules. Indeed it was surprising that detergent enzymes having an alkaline pH activity optimum could be stabilized by acidic compounds. Normally one would expect that an enzyme which functions optimally at alkaline pH would prefer and be more stable in an alkaline environment of for example alkaline buffer salts.

Izawa relates to an enzyme-containing granulated product containing, in a uniformly dispersed state, an enzyme and one or more stabilizers including reducing agents and antioxidants.

Bertacchi relates to a liquid composition suitable for bleaching fabrics including a peroxygen bleach, from 0.001% to 10% by weight of the total composition of propyl gallate, and from 0.001% to 10% by weight of an antioxidant.

Initially, Applicants note that Izawa is deficient as a reference. In particular, the record is clear that nowhere does Izawa show that at least 50% of the core is one or more of the specified acidic buffer components. Further, the Examiner has correctly stated that Izawa "fails to specifically disclose a core comprising citric acid or adipic acid, the amount of stabilizer within those recited, and the pH and pK_a values as those recited." No claim is obvious in light of Izawa alone.

Bertacchi fails to cure the deficiencies of Izawa. The Examiner, without any scientific evidence or appropriate rationale has concluded that Bertacchi is analogous prior art, and teaches the equivalency of ascorbic acid with citric acid or adipic acid as antioxidants for use in granules. Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. Here there is no detailed rationale given by the Examiner other than the assumption that one of skill in the art would have applied the acids of Bertacchi as antioxidants in granulation.

Further, it is speculative that the constituents in a liquid bleaching agent of Bertacchi would be excellent in an enzyme granule. The science associated with granule stability is unpredictable. One of ordinary skill in the art would not envision the success of using constituents in a liquid bleaching formula of Bertacchi in an enzyme granule. Further, there is no disclosure that the acidic buffer component would promote stability in an enzyme granule. A skilled person in the art would have no reasonable expectation of success that any component in a liquid bleach formulation could be effectively used to promote stability of an enzyme granule.

The combination of cited references does not provide the requisite teaching, suggestion and motivation to use the acids of Bertacchi in the Izawa reference. Certainly there is no scientific evidence or sound scientific reasoning offer by the Office to do so. The Office has improperly undermined the requirement for a reasonable expectation of success. More specifically, the conclusive statements offered by the Office are devoid of scientific reasoning.

Applicant further notes that the Examiner has not provided a sufficient reason or explicit analysis of why the disclosures of the references should be combined. The cited references are devoid of any suggestion to combine the teachings and suggestions of Izawa and Bertacchi as advanced by the Examiner, except from using Applicants' disclosure as a template through hindsight reconstruction of Applicant's claim. Thus, the Examiner has erroneously retraced the path of the inventor with hindsight --discounting the number of complexities of the alternatives in order to conclude that the specifically claimed granule was obvious. This reasoning is always inappropriate for an obviousness test based on the language of Title 35 that requires the

analysis to examine "the subject matter as a whole" to ascertain if it "would have been obvious at the time the invention was made." 35 U.S.C. § 103(a).

Applying a non-rigid TSM analysis, one of ordinary skill in the art would not be motivated by the references to substitute the constituents of Izawa for the acids of the Bertacchi liquid bleach compositions to somehow arrive at the Applicant's claimed invention. There is certainly no suggestion to do so.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. § 103(a). Applicants respectfully request reconsideration and withdrawal of the rejection.

V. The Rejection of Claims 27-28 under 35 U.S.C. 103(a)

Claims 27-28 stand rejected as obvious in light of Izawa, Bertacchi, and Rahman.

Claims 27-28 depend upon Claim 18, and are not obvious for the same reasons Claim 18 is not obvious.

VI. New Claim 40

New claim 40 is added. No new matter is added. Should any additional fee be due, the USPTO is authorized to charge the deposit account of Novozymes North America, Inc., *i.e.*, Deposit Account No. 50-1701.

VII. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application. Should any additional fees be due, the USPTO is authorized to charge the deposit account of Novozymes North America, Inc., *i.e.*, deposit account No. 50-1701.

Respectfully submitted,

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